

AUTHORIZATION LETTER

Wr. Neudorf, 09.02.2021

TO WHOM IT MAY CONCERN

We, **DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.**, headquarter in Austria, IZ-NÖ Süd, Hondastrasse Obj. M55, A-2351 Wr. Neudorf hereby declares that the below mentioned company is our official **representative** and is authorized to register, sell and distributor our products in the territory of Moldavia:

ECHIPAMED PLUS SRL
Valea Trandafirilor str., 24B, of.80,
MD-2001 Chisinau, Moldova

This certificate remains in force from 01.01.2021 until 31.01.2022 or is terminated during that period on the expiry of not less than 30 days' notice in writing given by either party to the other.

Signed for and on behalf of
DIALAB GmbH



Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H. & Co KG, IZ-NÖ Süd, Hondastrasse Obj. M55, 2351 Wr. Neudorf, Austria. Tel: +43 (0) 2236 660910-0 Fax: +43 (0) 2236 660910-30 Mail: office@dialab.at www.dialab.at

Christina ERNST
Export Manager

DIALAB Produktion und Vertrieb
von chemisch-technischen
Produkten und Laborinstrumenten
Gesellschaft m.b.H.

IZ-NÖ Süd
Hondastrasse, Objekt M55
2351 WR. NEUDORF
AUSTRIA

Phone: +43(0)2236 660910-0
Fax: +43(0)2236 660910-30
Mail: office@dialab.at
www.dialab.at

Managing Director / Geschäftsführer
Murat Estelik, Dipl. Ing. Marlene Ramsey
FN 108 078p | Landesgericht Wr. Neustadt
UID/VAT: ATU 150 136 06 | DVR: 0130985

Raiffeisen Regionalbank Moedling
BIC / SWIFT: RLNWAT3333
IBAN AT: AT97 3725 0000 0000 6739
IBAN USD: AT52 3225 0000 0000 6739



EC DECLARATION OF CONFORMITY

We



Dialab Produktion und Vertrieb von chemisch-technischen Produkten und
Laborinstrumenten Gesellschaft m.b.H.
IZ NOE-Sued, Hondastrasse, Objekt M55
2351 Wr. Neudorf, Austria

declare, on our own responsibility, that our products specified in the enclosed
addendum "Devices other than those covered by Annex II (Rapid Tests),
Rev.12 (3 pages)", classified as follows according to the directive on in vitro
diagnostic medical devices 98/79/EC:

Devices other than those covered by Annex II (Rapid Tests)

meet the applicable provisions of the European Directive 98/79/EC for in-vitro-
diagnostic medical devices and the Austrian Medical Product Law.

This Declaration is based on Conformity Assessment Procedures according to
Annex III of the aforesaid Directive.

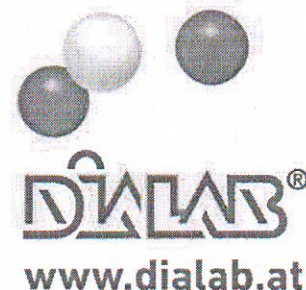
This Declaration is valid until 2022-03-28.

Wr. Neudorf, 2019-04-02



DI Marlene Ramsey
Managing Director

Addendum to the Declaration of Conformity of Devices other than those covered by Annex II (Rapid Tests)



Cardiac Markers

	REF	Content
DIAQUICK Cardiac Combo Cassette	Z08234CE	- 20 Tests (20x REF Z08233B)
	Z08233CE	- 5 Tests (5x REF Z08233B)
DIAQUICK Troponin I Cassette	Z08120CE	- 30 Tests (30x REF Z08120B)
	Z08125CE	- 5 Tests (5x REF Z08120B)

Tumour Markers

	REF	Content
DIAQUICK AFP Cassette	Z06020CE	- 30 Tests (30x REF Z03020B)
		- 2x 3 mL Buffer
DIAQUICK CEA Cassette	Z06030	- 30 Tests (30x Z03030B)
		- 2x 3 mL Buffer
DIAQUICK FOB Cassette	Z01101CE	- 25 Tests (25x Z01101B)
		- 25 Collection Tubes with Buffer
	Z01102CE	- 5 Tests (5x REF Z01101B)
		- 5 Collection Tubes with Buffer
DIAQUICK FOB-TRF Combi Cassette	J13101CE	- 20 Tests (20x J13101BN)
		- 20 Collection Tubes with Buffer

Pregnancy / Fertility

	REF	Content
DIAQUICK hCG Cassette	Z98404CE	- 30 Tests (30x REF Z98404B)
DIAQUICK hCG Dipstick (5 mm)	J01402-1CE	- 50 Tests (50x REF J01402-1B)
DIAQUICK hCG Dipstick (3 mm)	J01402-2CE	- 50 Tests (50x REF J01402-2B)
DIAQUICK hCG Combo Cassette	Z01405CE	- 30 Tests (30x REF Z01405B)
DIAQUICK hCG Combo Dipstick (5 mm)	Z03403-1CE	- 50 Tests (50x REF Z03403-1B)
DIAQUICK hCG Combo Dipstick (3 mm)	Z03403-2CE	- 50 Tests (50x REF Z03403-2B)
DIAQUICK LH Cassette	Z98502CE	- 30 Tests (30x REF Z98502B)
DIAQUICK LH Dipstick	Z06507CE	- 50 Tests (50x REF Z06507B)

Others

	REF	Content
DIAQUICK CRP Cassette	Z06021	- 20 Tests (20x REF Z06021B)
		- 20 Extraction Tubes with Buffer
DIAQUICK Microalbumin Dipstick	Z08070CE	- 50 Tests (50x REF Z08070B)

Infectious Diseases - ToRCH

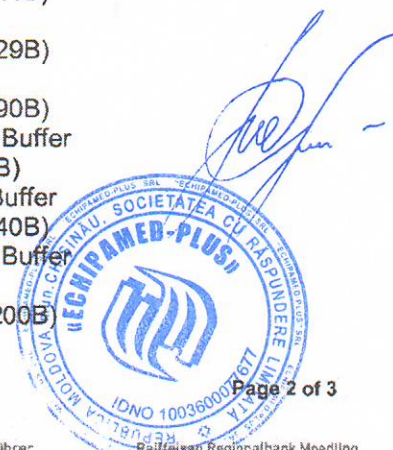
DIAQUICK HSV 1/2 IgM Cassette	J15040CE	- 25 Tests (25x REF J15040B)
		- 1x 3 mL Buffer

Other Infectious Diseases

	REF	Content
DIAQUICK Adenovirus Cassette	Z09620CE	- 5 Tests (5x REF Z09620B)
		- 5 Collection Tubes with Buffer
DIAQUICK Dengue IgG/IgM Ab Cassette	Z06240	- 30 Tests (30x REF Z06240B)
		- 1x 3 mL Buffer
DIAQUICK Dengue NS1 Ag Cassette	Z17240CE	- 30 Tests (30x REF Z17240B)
DIAQUICK Dengue Combo Cassette	Z17241CE	- 20 Tests (20x REF Z17241B)
		- 1x 3 mL Buffer
DIAQUICK H.pylori Cassette	Z06229CE	- 30 Tests (30x REF Z98229B)
		- 1x 3 mL Buffer
DIAQUICK H.pylori Stool Cassette	Z08090CE	- 20 Tests (20x REF Z08090B)
		- 20 Collection Tubes with Buffer
	Z08091CE	- 5 Tests (5x REF Z08090B)
		- 5 Collection Tubes with Buffer
DIAQUICK Influenza Ag Dipstick	Z09440CE	- 25 Tests (25x REF Z09440B)
		- 25 Collection Tubes with Buffer
		- 3 Control Swabs
DIAQUICK Malaria P.f. Cassette	W06200	- 30 Tests (30x REF W04200B)
		- 2x 3 mL Buffer

Rev.12

2019-04-02



Addendum to the Declaration of Conformity of Devices other than those covered by Annex II (Rapid Tests)

DIAQUICK Malaria P.f./Pan Cassette	Z11200CE	- 25 Tests (25x REF Z11200B) - 1x 3 mL Buffer
DIAQUICK Mononucleosis Cassette	Z06620CE	- 30 Tests (30x REF Z05620B) - 1x 5 mL Buffer - 1x 1 mL Positive Control - 1x 1 mL Negative Control
DIAQUICK Rotavirus Cassette	Z09610CE	- 5 Tests (5x REF Z09610B) - 5 Collection Tubes with Buffer
DIAQUICK Rota/Adeno Combi Cassette	Z09600CE	- 5 Tests (5x REF Z09600B) - 5 Collection Tubes with Buffer
	Z09601CE	- 30 Tests (30x REF Z09600B) - 30 Collection Tubes with Buffer
DIAQUICK Strep.A Cassette	Z98223CE	- 20 Tests (20x REF Z98223B) - 1x 10 mL Extraction Reagent A - 1x 10 mL Extraction Reagent B - 1x 1 mL Positive Control - 1x 1 mL Negative Control
DIAQUICK Strep.A Dipstick	Z98230CE	- 20 Tests (20x REF Z98230B) - 1x 10 mL Extraction Reagent A - 1x 10 mL Extraction Reagent B - 1x 1 mL Positive Control - 1x 1 mL Negative Control
DIAQUICK Syphilis Cassette	Z06903CE	- 30 Tests (30x REF Z03903B) - 2x 3 mL Buffer
DIAQUICK Syphilis Dipstick	Z12903CE	- 25 Tests (25x REF Z12903B) - 1x 3 mL Buffer
DIAQUICK S.typhi IgG/IgM Ab Cassette	Z11450	- 25 Tests (25x REF Z11450B) - 1x 6 mL Buffer
DIAQUICK S.typhi/paratyphi Ag Cassette	Z11451	- 25 Tests (25x REF Z11451B) - 25 Collection Tubes with Buffer



[Handwritten signature]

EC DECLARATION OF CONFORMITY

We



Dialab Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m. b. H.
IZ-NÖ Süd, Hondastrasse, Objekt M55
2351 Wiener Neudorf, Austria

declare, on our own responsibility, that our products specified in the enclosed addendum “Devices other than those covered by Annex II (Serology), Rev.08 (3 pages)”, classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC:

Devices other than those covered by Annex II (Serology)

meet the applicable provisions of the European Directive 98/79/EC for in-vitro-diagnostic medical devices and the Austrian Medical Product Law.

This Declaration is based on Conformity Assessment Procedures according to Annex III of the aforesaid Directive.

This Declaration is valid until 2022-03-28.



DIALAB
Produktion und Vertrieb von chemisch – technischen
Produkten und Laborinstrumenten Gesellschaft m.b.H.
A - 2351 Wiener Neudorf, IZ-NÖ Süd, Hondastr. Obj.M55
Phone: +43 (0) 2236 660910-0 Fax: +43 (0) 2236 660910-30
E-Mail: office@dialab.at Website: www.dialab.at

Wr. Neudorf, 2019-04-02

DI Marlene Ramsey
Managing Director

Addendum to the Declaration of Conformity of Devices other than those covered by Annex II (Serology)



Latex- and Haemagglutination

	REF	Content
ASO	603401	- 1x 5 mL Latex Reagent - 1x 1 mL Positive Control - 1x 1 mL Negative Control
	603403	- 1x 2.5 mL Latex Reagent - 1x 1 mL Positive Control - 1x 1 mL Negative Control
ASO Latex Reagent	603421SV	- 1x 5 mL
CRP	603405	- 1x 2.5 mL Latex Reagent - 1x 1 mL Positive Control - 1x 1 mL Negative Control
	603407	- 1x 5 mL Latex Reagent - 1x 1 mL Positive Control - 1x 1 mL Negative Control
CRP Latex Reagent	603422SV	- 1x 5 mL
IM	495038	- 1x 2.5 mL Latex Reagent - 1x 1 mL Positive Control - 1x 1 mL Negative Control
	414010	- 1x 2.5 mL Latex Reagent - 1x 0.5 mL Positive Control - 1x 0.5 mL Negative Control
RF	603409	- 1x 5 mL Latex Reagent - 1x 1 mL Positive Control - 1x 1 mL Negative Control
	603411	- 1x 2.5 mL Latex Reagent - 1x 1 mL Positive Control - 1x 1 mL Negative Control
RF Latex Reagent	603423SV	- 1x 5 mL
Waler Rose	495056	- 1x 2.5 mL Latex Reagent - 1x 1 mL Positive Control - 1x 1 mL Negative Control
	495055	- 1x 5 mL Latex Reagent - 1x 1 mL Positive Control - 1x 1 mL Negative Control

Syphilis Tests

	REF	Content
Syphilis RPR	495015	- 1x 3 mL RPR Carbon Reagent - 1x 1 mL Positive Control - 1x 1 mL Negative Control
	495016	- 2x 5 mL RPR Carbon Reagent - 1x 1 mL Positive Control - 1x 1 mL Negative Control
Syphilis RPR Carbon Reagent	408320SV	- 1x 5 mL RPR Carbon Reagent
Syphilis TPHA	401040	- 1x 8.5 mL Test Cells - 1x 8.5 mL Control Cells - 1x 20 mL Diluent - 1x 1 mL Positive Control - 1x 1 mL Negative Control
	408050	- 2x 8.5 mL Test Cells - 2x 8.5 mL Control Cells - 2x 20 mL Diluent - 1x 1 mL Positive Control - 1x 1 mL Negative Control
	408060	- 1x 42.5 mL Test Cells - 1x 42.5 mL Control Cells - 2x 50 mL Diluent - 1x 5 mL Positive Control - 1x 5 mL Negative Control
Syphilis VDRL	497073	- 1x 5 mL VDRL Antigen Reagent - 1x 1 mL Positive Control - 1x 1 mL Negative Control
	401075	- 1x 30 mL VDRL Antigen Reagent - 1x 1 mL Positive Control - 1x 1 mL Negative Control

EC DECLARATION OF CONFORMITY

We



Dialab Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m. b. H.
IZ-NOE Sued, Hondastrasse, Objekt M55
2351 Wiener Neudorf, Austria

declare, on our own responsibility, that our products specified in the enclosed addendum "Other Products (Blood Grouping), Rev.09 (1 page)", classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC:

Devices other than those covered by Annex II (Blood Grouping)

meet the applicable provisions of the European Directive 98 / 79 / EC for in-vitro diagnostic medical devices and the Austrian Medical Product Law

CE marking has been carried out following the procedure referred to in Annex III of the aforesaid Directive.

This declaration is valid until 2022-03-28.

DI Marlene Ramsey
Managing Director

Wiener Neudorf, 2019-04-08

DI Marlene Ramsey
Managing Director

Addendum to the Declaration of Conformity for Other Products (Blood Grouping)

BLOOD GROUPING AND RHESUS TYPING

ABO and Rhesus Typing	REF	CONT
Anti-Cv, monoclonal	B13001	1x 2 mL
Rare Blood Grouping Reagents		
Anti-H Lecln	B09934	1x 2 mL
Anti-k, monoclonal	B18908	1x 2 mL
Auxiliary Reagents		
BSA 22%	B05176	1x 10 mL
BSA 30%	B05175	1x 10 mL
LISS solution	B05178	1x 10 mL
Papain	B08000	1x 10 mL
Papain	B08001B	1x 1 L

DI Marlene Ramsey



Other Products (Blood Grouping), Rev.08

Page 1 of 1